APPENDIX B

INTRODUCTION
TO
THE U.S. ARMY CORPS OF ENGINEERS
VALIDATION PROGRAM
FOR
COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES

(SAMPLE LETTER)

Dear Laboratory Director:

Thank you for your interest in the U.S. Army Corps of Engineers (USACE) Hazardous, Toxic, and Radioactive Waste (HTRW) laboratory validation program. I hope that the information enclosed will be helpful to you and answer any questions you may have.

If you have any further questions regarding this information or the USACE HTRW laboratory validation program in general, please contact the USACE Laboratory Validation Coordinator at (402) 221-7494.

Sincerely,

Chief, Environmental, HTRW Division
HTRW and Engineering Directorate

Enclosure

INTRODUCTION TO THE U.S. ARMY CORPS OF ENGINEERS VALIDATION PROGRAM FOR COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES

WHO NEEDS VALIDATION?

According to USACE Engineer Regulation 1110-1-263, CHEMICAL DATA QUALITY MANAGEMENT FOR HAZARDOUS WASTE REMEDIAL ACTIVITIES:

> Laboratory validation shall apply to all commercial laboratories directly or indirectly providing chemical analysis support to USACE HTRW investigative and remedial activities.

All commercial laboratories that support USACE HTRW response activities must obtain a USACE laboratory validation prior to field studies or sample analyses and must maintain the validated status throughout the contract/project/task order(s) (hereafter referred to as the contract or project) for the HTRW response activities.

HOW TO APPLY FOR A VALIDATION

After a prime architect-engineering firm or a construction contractor (hereafter referred to as the prime contractor) is awarded with a contract to support USACE HTRW remedial activities, the prime contractor will select a subcontract commercial laboratory for this contract and notify the USACE Technical Manager or Contracting Officer Representative (TM/COR) of its selection. The USACE TM/COR will then submit a written request for evaluation of the subcontract commercial laboratory to the USACE Laboratory Validation Committee (hereafter referred to as the Committee) to initiate the laboratory validation process. After receipt of the request, the Committee will contact the laboratory shortly. A commercial laboratory, itself, does not apply for a USACE HTRW laboratory validation. The Committee will only respond to a validation request from a USACE TM/COR.

WHAT IS THE VALIDATION PROCESS?

The laboratory validation process consists of three major sequential steps: (1) the Committee reviews the laboratory's qualification documents, (2) the laboratory analyzes a set of performance evaluation (PE) samples, and (3) the Committee conducts an on-site laboratory inspection. The Committee is

responsible for execution and management of the laboratory validation program.

WHAT KIND OF QUALIFICATION DOCUMENTS?

Typical qualification documents may be in the form of an off-the-shelf laboratory quality management manual (LQMM) or in some other format which includes a laboratory floor plan, organization chart, instrumentation list, staff resumes, certificates, in-house standard operating procedures, etc. The documents should provide proper information for the Committee to assess the laboratory's technical capabilities. Upon request, a laboratory should promptly submit its qualification statements to the Committee for review. If it appears that the laboratory has the adequate capabilities to meet project requirements, the Committee will initiate the next step, PE sample analysis.

WHAT KIND OF PE SAMPLES?

The Committee will provide the laboratory with project-specific PE samples for performance evaluation. The PE samples may be in water and/or soil/sediment matrices. Arrangements will be made with the laboratory for analysis and reporting of these samples. The results are considered passing if the results of a particular method are within statistically established acceptance limits as determined by the USACE and no procedural problems are found during a follow-up laboratory inspection. A laboratory may volunteer for additional non-project-specific PE samples at its own cost. A laboratory must pass more than 50 percent of all PE samples within 40 working days from receipt of the PE samples or the validation process will be terminated.

WHAT ARE INSPECTION PROCEDURES?

Two Committee representatives will inspect the laboratory only after Steps 1 and 2 have been satisfactorily completed. The on-site inspection which generally takes eight hours includes: (1) an entrance interview with the laboratory management to discuss USACE QA program, review comments on laboratory qualification submittals including LQMM, PE sample results, upcoming projects, etc., (2) a follow-up laboratory tour to examine laboratory facility, instrumentation, operation, maintenance, documentation, etc., and (3) an exit interview to summarize any deficiencies found and corrective actions required. A laboratory must rectify any deficiencies noted during the inspection prior to an approval for a full validation status.

After inspection, the Committee will meet to review and determine the validation status of a laboratory.

WHAT ARE VALIDATION CRITERIA?

The USACE basically follows Federal and/or State laws, regulations, and guidelines and good laboratory practices to evaluate laboratory performance. The validation status of a laboratory depends on whether the laboratory's PE sample results are within USACE established acceptance criteria and no procedural problems are found during a follow-up laboratory inspection. The laboratory's PE sample results will be compared in the following manner: (1) with the prepared concentrations of PE samples that are used as the absolute recovery comparators, and (2) with the statistical mean and standard deviations reported by a group of peer laboratories. The acceptable limits for analyte quantitation will be established statistically at 95 percent confidence based on referee laboratories' and/or peer group results.

HOW MUCH TIME DOES VALIDATION TAKE?

The entire process of laboratory validation generally takes up to 12 weeks depending on a laboratory's performance and responsiveness. The prime contractors should plan the project schedule to allow adequate time for laboratory validation process.

WILL A CERTIFICATE BE ISSUED?

USACE will not issue a certificate for validated laboratories. However, a letter and a copy of inspection report will be sent to each validated laboratory. The letter will specify the methods and matrices, the project(s), and the time period (usually 18 months) for which the validation is granted.

IS THE VALIDATION UNIVERSAL?

The validation is a parameter, method, and matrix-specific approval and only applies for USACE HTRW program. However, for each new contract awarded during the 18-month validation period, a project-specific evaluation is still required. The Committee will check the laboratory's validation status and previous performance to determine if any additional actions are needed. If different parameters, methods, and/or matrices are involved,

only those PE samples will be sent. If work done for the USACE by the laboratory has been satisfactory, no further actions will be necessary.

HOW ABOUT SUBCONTRACTING?

A validated laboratory may not subcontract any USACE samples to a second laboratory without the knowledge and approval of the USACE TM/COR and the concurrence of the Committee. The second laboratory must also be validated for methods, parameters, and matrices corresponding to the subcontract. Subcontract of PE sample analysis is totally prohibited.

WHAT ARE THE FEES REQUIRED FOR VALIDATION?

There are no direct fees for the laboratory besides the cost for additional PE samples required for failed parameters or non-project-specific parameters. The current cost for any additional or any non-project-specific PE samples ranges from $100 to $300 per method, per matrix, and per shipment. The cost shall be reviewed annually and adjusted as necessary without notice to reflect currency value fluctuations or changes in program administration costs. The USACE will not pay the costs for analysis of PE samples and preparation of any qualification documents.

WHERE TO GET MORE INFORMATION

The Laboratory Validation Committee at the USACE HTRW Mandatory Center of Expertise (MCX) of the USACE is responsible for all aspects of the USACE HTRW laboratory validation program. The Committee meets as needed to propose policy on USACE HTRW laboratory validation program and to make ultimate decisions on laboratory-specific validation status. Any questions concerning the validation program can be directed to the Laboratory Validation Coordinator.

U.S. Army Corps of Engineers
HTRW Mandatory Center of Expertise
ATTN: CEMRD-ED-EC (Laboratory Validation Coordinator)
12565 West Center Road
Omaha, NE 68144-3869

Voice: (402) 221-7494
FAX : (402) 221-7403